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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,790	04/08/2005	Hideko Kosaka	10873.1670USWO	9379

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EXAMINER	
WHITE, DENNIS MICHAEL	
ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
01/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,790	KOSAKA, HIDEKO	
	Examiner	Art Unit	
	DENNIS M. WHITE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 12-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/04/2008 has been entered. Claim 1 is amended, claims 9-11 and 17-18 are cancelled. Currently claims 1-8 and 12-16 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-8, 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al (Chem. Pharm. Bull 1983), hereinafter “Mori”, in view of Kosaka (US 2002/0037591).

Regarding claims 1-2, 7-8, 12-15, Mori teaches reagents for a spectrophotometric determination of creatinine ("test for creatinine measurement comprising") comprising a color indicator 0-hydroxyhydroquinonephthalein, hereinafter "Qn.Ph." and palladium(II) that forms a complex together. The Qn.Ph. solution is 0.001 mol/liter, palladium(II) is 0.0005, therefore the ratio is 2:1 and has been read on claim 12. The test further comprises a buffer solution of 0.2M acetic acid and 0.2M sodium acetate. The ratio is 1:200 of indicator to buffer and has been read on claim 14 (Pg. 1389). Mori teaches the test further comprises surfactants of 1.0mL of 1.0% PVA and 1.0mL of 1.0% SDS in a total volume of 10mL. Mori is silent that the reagents are on a test piece, the compound is in a porous material, and the color indicator is pyrocatechol violet, chromazurol S, or chromazurol B, and the compound to surfactant molar ratio is 50:1 to 3:1.

Kosaka teaches a composition for detecting trace amount of protein comprising an indicator reagent and a transition element. The indicator reagent and the transition element form a complex that then is used to show a color change indicating the presence of a protein. (Abstract) The reagent composition is suited for the measurement under wet conditions as a liquid reagent and also under dry conditions in which the reagent composition is uniformly incorporated into a carrier comprising water-absorbable porous materials such as filter paper. It is desirable to provide the reagents on a carrier with porous materials because it allows for the reagent composition to be included in the carrier uniformly over its entire portion at predetermined concentrations so that the liquid protein concentration can accurately be determined (Para. 0023). The

indicators dye that are known to form a complex with a transition metal that binds to a protein to shift the wavelength comprise dyes such as pyrocatechol violet (“formula (1)" “formula (2)" and "formula (7)”) and o-hydroxyhydroquinone phthalein or “Qn.Ph” (Para. 0025). Kosaka teaches the surfactant can be in an amount of the surfactant in the reagent composition from about 0.001 to 1% by weight.

Therefore it would have been obvious to one of ordinary skill in the art, as motivated by Kosaka, to provide the reagents of Mori in the porous material carrier of Kosaka in order to for the reagent composition to be included in the carrier uniformly over its entire portion at predetermined concentrations so that the liquid protein concentration can accurately be determined.

Therefore it would have been obvious to one of ordinary skill in the art, as motivated by Kosaka, to substitute the Qn.Ph. of Mori with the pyrocatechol violet of Kosaka in order to provide a well known indicator capable of forming a complex with a transition metal ion that binds to a protein to shift the wavelength and be able to detect trace amounts of the protein.

Regarding claims 3-6, Mori/Kosaka teach the compound pyrocatechol violet (formula 7). Mori/Kosaka are silent about the compound is Chromazurol S (formula 3 and 4), Chromazurol B (formula 5), and Eriochrome cyanine (formula 6). Structural similarities have been found to support a prima facie case of obviousness. See, e.g., In re May, 574 F.2d 1082, 1093-95, 197 USPQ 601, 610-11 (CCPA 1978) (stereoisomers); In re Wilder, 563 F.2d 457, 460, 195 USPQ 426, 429 (CCPA 1977) (adjacent homologs and structural isomers); In re Hoch, 428 F.2d 1341, 1344, 166 USPQ 406, 409 (CCPA

1970) (acid and ethyl ester); In re Druey, 319 F.2d 237, 240, 138 USPQ 39, 41 (CCPA 1963) (omission of methyl group from pyrazole ring). Generally, some teaching of a structural similarity will be necessary to suggest selection of the claimed species or subgenus. See also In re Hoeksema, 399 F.2d 269, 158 USPQ 596 (CCPA 1968) (A claim to a compound was rejected over a patent to De Boer which disclosed compounds similar in structure to those claimed (obvious homologs) and a process of making these compounds).

Therefore, it would have been obvious to one of ordinary skill to substitute chromazurol B, chromazurol S, and Eriochrome cyanine R as known equivalents of or pyrocatechol violent to obtain the expected result of indicators capable of color changes.

Regarding claim 16, Mori and Kosaka fail to teach the claimed ratio of compound to surfactant. *In re Boesch* (205 USPQ 215) teaches the optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The choice of a surfactant is a result effective variable that gives the well known and expected results of managing the surface characteristics of the reactants. It is desirable to provide surfactant at levels that increase the reactivity without interfering with protein measurement (Kosaka: Para. 0031).

Therefore it would have been obvious to provide the ratio of compound to surfactant in the ratio of 50:1 to 3:1 in order to provide an amount of surfactant to

increase the reactivity without interfering with the measurement and as optimization of a result effective variable.

Response to Arguments

5. Applicant's arguments with respect to claims 1-8, 12-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

/dmw/